K073071

FEB - 6 2009

1. 510(k) SUMMARY

Feb 6, 2009

Contact

Dr. Howard Doong
TrimGen Corporation
34 Loveton Circle, Suite 210
Sparks, MD 21152

NAME OF DEVICE

Trade Name: eQ-PCR™ LC Warfarin Genotyping kit
Regulation Number: 21 CFR 862.3360
Classification Name: Drug metabolizing enzyme genotyping system

PREDICATE DEVICE

Verigene® Warfarin Metabolism Nucleic Acid Test (K070804)

INTENDED USE

The eQ-PCR™ LC Warfarin Genotyping kit is an in vitro diagnostic test for the detection and genotyping of two single nucleotide polymorphisms (SNP) in the cytochrome P450 enzyme gene CYP2C9 known as CYP2C9*2 (C430T) and CYP2C9*3 (A1075C), and a SNP in the vitamin K epoxide reductase complex 1 gene VKORC1, known as VKORC1 (–1639G>A) obtained from human peripheral blood samples. The eQ-PCR LC Warfarin Genotyping kit is a qualitative assay for use in clinical laboratories upon prescription by the attending physician.

The eQ-PCR™ LC Warfarin Genotyping kit is indicated for use as an aid in identifying patients who may be at risk of warfarin sensitivity.

PRODUCT DESCRIPTION

The eQ-PCR™ LC Warfarin Genotyping Kit assay requires extracted DNA obtained by using any commercially available DNA extraction kit. The extracted DNA sample, within a range of 50-200ng of total DNA, is mixed with a PCR Mix, and an eQ-PCR™ specific Probe Mix reagent containing specific primers and fluorescent labeled probes for the CYP2C9 and/or VKORC1 gene polymorphisms. Amplification and detection are then performed in the Roche Diagnostics LightCycler® Real-Time PCR System instrument model 1.2 using conditions defined in the specific eQ-PCR™ LC Warfarin Genotyping Kit Product Insert. After the PCR reaction is completed, the Roche Diagnostics LightCycler® Real-Time PCR System instrument automatically proceeds to the melting curve-based detection method. This real time PCR test is a closed test system and does not require post PCR operations. It reduces human errors and eliminates post-PCR handling contamination.

The instrument's standard melting curve analysis software algorithm of peak patterns and melting temperatures (Tm) determine the genotype (wild type, mutant, heterozygous) for each of the three specified polymorphisms.

SUBSTANTIAL EQUIVALENCE

Clinical Performance

A clinical trial was conducted to test the performance of the eQ-PCR™ LC Warfarin Genotyping Kit compared to bi-directional sequencing using extracted nucleic acid from whole blood from 159 donors. Two EDTA-anticoagulated whole blood samples were collected from each of 159 adult volunteers. The samples were collected under IRB approval and with Informed Consent. The whole blood samples were extracted at a reference laboratory. The extracted DNA from the two samples from the same matrix per donor was pooled for testing in the study. Bi-directional sequencing was performed at a reference laboratory on the 159 DNA samples extracted from the whole blood samples.

Aliquots of the extracted nucleic acid samples were prepared at TrimGen at a concentration of 10ng/μL. Each testing site received aliquots of 50 whole blood (WB) DNA, and 9 commercial control DNA samples. The donor samples tested at each site were unique to that site and did not duplicate the donors at the other two sites. Ten (10) WB samples were tested with the eQ-PCR™ LC Warfarin Genotyping Kit and the Roche LightCycler each day for a total of 5 testing days.

The results for the whole blood testing are summarized below.

SNP	Genotype	Clinical Sensitivity		95% Confidence Interval
		#	%	
2C9*2	Wild Type	123/126	97.6%	94.40%
	Heterozygous	27/28	96.4%	87.68%
	Variant	5/5	100%	47.98%
2C9*3	Wild Type	138/140	98.6%	96.09%
	Heterozygous	12/13	92.3%	75.32%
	Variant	5/6	83.3%	54.28%
VKORC1	Wild Type	77/79	97.5%	93.16%
	Heterozygous	62/63	98.4%	94.32%
	Variant	17/17	100%	80.52%

The initial results showed overall 99.6% clinical sensitivity of the eQ-PCR™ LC Warfarin Genotyping Kit compared to bi-directional results for the whole blood samples. Only 0.4% (2/450) of the results was discordant and resolved in agreement with the eQ-PCR™ LC Warfarin Genotyping Kit result when bi-directional sequencing was repeated. After re-sequencing the discrepant samples, the overall result demonstrates 100% clinical sensitivity of the assay's substantial equivalence to bi-directional sequencing.

Reproducibility

A study was conducted at two external sites and at TrimGen Corporation to determine the reproducibility of the eQ-PCR™ LC Warfarin Genotyping Kit across days, operators, and sites. A panel of 31 samples was extracted and tested at each of the three sites on each of five days. The panel consisted of whole blood samples. At all sites, separate operators performed the testing on alternate days.

There was no discordance among observed results or between observed and expected results across sites, days or operators. All whole blood and controls gave consistent eQ-PCR™ LC Warfarin Genotyping Kit results within days, across days, across operators, and across sites. In addition, all genotyping results matched the bi-directional sequencing results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

TrimGen Corporation
c/o Dr. Howard Doong
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34 Loveton Circle #210
Sparks, MD 21152

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Re: k073071
Trade/Device Name: eQ-PCR™ LC Warfarin Genotyping Kit
Regulation Number: 21 CFR 862.3360
Regulation Name: Drug metabolizing enzyme genotyping system.
Regulatory Class: Class II
Product Code: ODW, NSU, ODV
Dated: January 20, 2009
Received: January 23, 2009

Dear Dr. Doong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K073071

Device Name: eQ-PCR LC Warfarin Genotyping Kit

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073071